DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administratio

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

June 5, 2001

Reference: 2954475

John P. and Leanna J. Harder, Owners
Riverside Smoker
791 Riverside Park Road
Carlotta, California 95528

WARNING LETTER

Dear Mr. and Mrs. Harder:

We inspected your seafood processing facility on February 2, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations, Part 123 (21 CFR 123) and the current Good Manufacturing Practice (cGMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. The deficiencies cause your refrigerated, vacuum packed ready-to-eat, smoked Albacore tuna to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that the fish have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with Mrs. Leanna J. Harder at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deficiencies are as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your

firm's HACCP plan for Smoked Albacore Tuna does not list the food safety hazard of *Clostridium botulinum* toxin formation in finished product as a result of time/temperature abuse.

2. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3).

a) However, your firm's HACCP plan for hot smoked Albacore tuna does not list adequate critical limits at the Receiving CCP to control histamine formation as a result of time/temperature abuse, for fish received directly from the harvester.

b) However, your firm's HACCP plan for hot smoked Albacore tuna does not list adequate critical limits at the Brining critical control points (CCP) to control *Clostridium botulinum* toxin formation in the finished product as evidenced by the low water phase salt levels found in the sample of hot smoked Albacore tuna collected and analyzed by FDA during the current inspection of your firm.

3. You must have a HACCP plan that lists adequate monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Smoked Albacore lists a monitoring procedure at the Smoking/Cooking CCP that is not adequate to control *Clostridium botulinum* toxin formation. Specifically, only one fish loin is being monitored for internal temperature as evidenced by the HACCP monitoring records for Batch 191, dated 01/23.

4. You must implement the monitoring procedures and frequencies listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not monitor the salinity of the brining solution during the production of Batch 191.

5. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Brining CCP during the production of Batches 192 and 193. Additionally, you have no HACCP records to document monitoring of the Storage of Finished Product CCP.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

We acknowledge Mrs. Harder's February 8 and 25, 2001 responses to the inspectional observations presented to her at the close of the inspection. Her reply has been appended to your company file and we will verify the corrections at the next inspection. There are, however, other HACCP issues cited in this letter that need to be addressed immediately.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Darrell T. Lee
Acting Director
San Francisco District

Enclosure